REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested. Claims 1, 13, and 20 have been amended to remove several isoforms from the list. Therefore, no new questions of patentability should arise nor does the amendment necessitate any further searching on the part of the Examiner. The amendment places the application in condition for allowance. At a minimum, the amendment places the application in a better condition for appeal. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

Interview with the Examiner

The applicants appreciate the telephone interview between the applicants' representative and Examiner Goldberg on March 24, 2009. During the interview, the applicants' representative proposed amending the claims to recite that the gene coding for UGT1 has a nucleotide sequence that is common to each isoform of UGT1A1 and UGT1A6. The Examiner stated that the proposed amendment appeared on its face to overcome the outstanding rejection and that the amendment would likely be entered.

Rejection of claims 1-2, 5-6, 10, 13, and 19-21 under 35 U.S.C. §112 -- first paragraph

At pages 2-10 of the Office Action, the Examiner rejects claims 1-2, 5-6, 10, 13, and 19-21 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that Kurkela et al. compares the 1A9 and 1A6 isoforms and finds differences in the effect of the Y483D mutation between the two isoforms. The Examiner states that Kurkela specifically teaches that Y486D mutation was shown to reduce the activities of

UGT1A1 and UGT1A6. The Examiner indicates that it is unpredictable whether UGT1A3, UGT1A4, UGT1A5, UGT1A7, UGT1A8, or UGT1A9 would have similar enzyme activity in response to drug glucuronidation. This rejection is respectfully traversed.

The previous scope of the claims comply with the requirements of 35 U.S.C. §112 and are enabled for at least the reasons previously presented. However, in order to assist the Examiner, and without any admission as to the correctness of the rejection, the claims have been amended to recite that the gene coding for UGT1 has a nucleotide sequence that is common to each isoform of UGT1A1 and UGT1A6. The specification clearly shows that mutation in an exon 5 region of a gene coding for UGT1, having a nucleotide sequence that is common to each isoform of UGT1A1 and UGT1A6, decreases the enzymatic activity of the UGT1A1 and UGT1A6 isoforms (present application, pages 7 and 20-21).

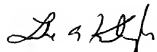
Accordingly, the rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



Luke A. Kilyk
Reg. No. 33,251

Atty. Docket No. 3190-074
KILYK & BOWERSOX, P.L.L.C.
400 Holiday Court, Suite 102
Warrenton, VA 20186
Tel.: (540) 428-1701
Fax: (540) 428-1720